

**REMARKS**

The Office Action states that the Claims of the present application belong to four (4) separate (independent and distinct) inventions, and requires a four-way restriction. Applicants respectfully traverse. For examination purposes, applicants provisionally elect, with traverse, Group I which include Claims 41-62. Further, for examination purposes, applicants elect the CMV promoter and hepatic cancer as the species to be initially examined.

As an initial matter, this application is the national stage of a PCT application, and accordingly, the PCT unity of invention standard, instead of that articulated in MPEP § 806, applies. The MPEP, following a court decision, see *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 USPQ 590 (E.D. Va. 1986), mandates that

“when the [U.S. Patent and Trademark] Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. ...

In applying PCT Rule 13.2 ... to national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching ... claims to the categories which meet the requirements of PCT Rule 13.2.

MPEP § 1850 (underlining added).

According to Rule 13.2, unity of invention exists when “there is a technical relationship among the claimed inventions involving one or more special technical features. The term ‘special technical features’ is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.” In the instant application, it is apparent that the inventions in all pending claims involve a special technical

feature, i.e., targeted overexpression of P450 in combination with acetaminophen for cell killing. As a consequence, all pending claims satisfy the unity of invention requirement under PCT Rule 13.2 and the restriction requirement is improper and should be withdrawn

Furthermore, applicants respectfully submit that the restriction between the claims in the alleged groups I and II is especially improper. The MPEP illustrated, in detail, three situations where unity of invention should be analyzed. See MPEP § 1850(B). One of the three situations is "Combinations of Different Categories of Claims:"

The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product;

Thus, a process shall be considered to be specially adapted for the manufacture of a product if the claimed process inherently results in the claimed product with the technical relationship being present between the claimed product and claimed process. The words "specially adapted" are not intended to imply that the product could not also be manufactured by a different process.

Also an apparatus or means shall be considered to be specifically designed for carrying out a claimed process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art. Consequently, it would not be sufficient that the apparatus or means is merely capable of being used in carrying out the claimed process. However, the expression specifically designed does not imply that the apparatus or means could not be used for carrying out another process, nor that the process could not be carried out using an alternative apparatus or means.

MPEP § 1850(C) (quoting PCT Administrative Rule 13) (underline added).

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The instant claims in the alleged Groups I and II are claims to the use of a given product and claims to that product, respectively, precisely the situation exemplified above. Accordingly, applicants respectfully submit that the restriction requirement is improper and should be withdrawn.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (CAM #: 010331.49927US).

Respectfully submitted,

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